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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 825,244	04/02/2001	Sharat Singh	0225-0033.24	2665

33603 7590 06/19/2003

ACLARA BIOSCIENCES, INC.
1288 PEAR AVENUE
MOUNTAIN VIEW, CA 94043

EXAMINER

TUNG, JOYCE

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 06/19/2003

31

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/825,244

Applicant(s)
Singh et al.

Examiner
Joyce Tung

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1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 19, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21, 22, 24, 25, 27, 28, and 30-36 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30-36 is/are allowed.
- 6) ☒ Claim(s) 21, 22, 24, 25, 27, and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 30 6) ☐ Other: _____

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DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/19/2003 has been entered. Following the entry of the amendment, claims 21, 22, 24-28, and 30-36 are pending.

Rejections and/or objected from the previous office action are hereby withdrawn. The following rejections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 21-22, 24, and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Ness et al. (6,027,890) in view Giese (Analytical Chemistry, 1983, Vol. 2(7) page 166-168).

Van Ness et al. disclose a variety of first and second member of a ligand pairs in which one or more members used in the method is tagged (See column 2, lines 14-27) and the tag is cleavable by oxidation (See column 4, lines 16-24). The ligand pair can be an antibody or antibody fragment (See column 2, lines 29-44). The tag is detectable by non-fluorescent spectrometry, or potentiometry (See column 2, lines 55 to column 3, lines 1-8) or the tag can be fluorescent labeled and detected by fluorometer (See column 3, lines 37-40). The labile linking group has thioethers, disulfide formation (See column 37, lines 12-26) and sulfoxide (See column 34, lines 39-46). There are more than 500 different and unique tagged molecules and each tag is unique for a selected nucleic acid fragment or first or second member and may be separately identified (See column 3, lines 29-36). The bound member and unbound member is separated by electrophoresis (See column 3, lines 58-67). The member ligand pair of Van Ness has the same components of the probe set.

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However, Van Ness et al. do not disclose eTag reporters from different electrophoretic probes form distinct peaks upon electrophoretic separation.

Giese disclose an electrophoric release tag which has the same components as the e-tag probe. The released tags comprise 3 molecular groups, known as 'signal', 'release' and 'reactivity' groups. The release group provides a site for specific covalent cleavage and the reactivity group attaches the release tag to a substance of interest (See pg. 166, column 1, first paragraph). Giese also addresses the benefit of using the tag (See pg. 166, column 1, third paragraph to column 2, first paragraph) and the potential usefulness in which the tag can be used for detecting antigen or haptens, a certain nucleic acid sequence and receptors (See pg. 167, column 1, second and third paragraph and column 2, second paragraph).

One of ordinary skill in the art at the time of the invention was made would have been motivated to apply electrophoretic separation of Giese in order to construct a set of electrophoretic tag probe. Giese states that Gas phase electrophores offer several useful properties as signal groups in chemical analysis and this method can be used in analyzing multiple target simultaneously (See pg. 168, column 1). This suggests that the released tag forms distinct peak upon electrophoretic separation. Thus it would have been prima facie obvious to apply the gas phase electrophores to the tagged member of Van Ness to construct the set of electrophoric release tag probe.

Regarding the argument filed 2/19/2003 concerning the references of Giese et al., the argument argues that many optically molecules, such as organic fluorescent molecules, are not

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available for use in Giese's method because such molecules decompose rather than volatilize at temperatures necessary for gas chromatography (See pg. 6 of the response filed 2/19/2003).

Since claim 1 does not specify what is the detection label for the detection group, the reference of Giese's is still applicable for claim 1.

4. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Van Ness et al. (6,027,890) as applied to claims 21-22, 24, 26-28 above in view Giese (Analytical Chemistry, 1983, Vol. 2(7) page 166-168) and further in view of Breslow et al. (6,331,530).

The teachings of Van Ness et al. and Giese are set forth in section 3 above and Breslow et al. (6,331,530).

The teachings of Van Ness et al. and Giese are set forth in section 3 above and Van Ness et al and Giese do not address the cleavable linkage which is cleaved by singlet oxygen.

Breslow et al. disclose a linker between two β -cyclodextrin molecules and that a photosensitizer is encapsulated within a matrix, wherein the cleavable linker is cleaved upon exposure to light (See the abstract). Singlet oxygen is produced to cleave the linker (See column 3, lines 47-51).

It have been prima facie obvious to an ordinary skill in the art at the time of instant invention to construct a probe set comprising a plurality of e-tag probes at the time of the instant invention for detecting the presence or absence of one or more target compounds containing cleavable linkage of which is cleaved by singlet oxygen because the active cleaving agent, singlet oxygen is used in the system of Breslow et al. for cancer therapy and this suggests

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that the active cleaving agent must be very efficient. Thus, an ordinary skill in the art would have combined the teachings of the references of Van Ness et al., Giese and Breslow et al. to make the probe set for detecting the presence or absence of one or more target compounds, and the probe set comprising a plurality of electrophoretic probes.

Allowable Subject Matter

5. Claims 30-36 are allowable.

Summary

6. Claims 21-22, 24-28 are not allowable.
7. The drawings filed 4/02/2001 are approved.
8. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal

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Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

June 16, 2003


ETHAN WHISENANT
PRIMARY EXAMINER